

**ASPIRIN- aspirin tablet, chewable**  
**Advance Pharmaceutical Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**ASPIRIN 81mg**

**Active Ingredient**

**(in each tablet)**

Aspirin 81 mg (NSAID) \*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain Reliever

**Use**

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effect may occur.

**Warnings**

**Reye's Syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early signs of Reye's syndrome, a rare but serious illness.

**Allergy Alert:** Aspirin may cause a severe allergic reaction which may include

- hives
- asthma (wheezing)
- shock
- facial swelling

**Stomach Bleeding Warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if your child

- has had stomach ulcers or bleeding problems
- take a blood-thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (ibuprofen, naproxen, others)
- takes more or for a longer time than directed

**Do not use**

- if the child has ever had an allergic reaction to any other pain reliever / fever reducer
- for at least 7 days after tonsillectomy or oral surgery

**Ask a doctor before use if**

- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting and diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, or kidney disease

- child is taking a diuretic
- child has asthma

**Ask a doctor or pharmacist before use if the child is**

- taking a prescription drug for diabetes, gout or arthritis
- taking any other drug
- under a doctor’s care for any serious condition

**Stop use and ask a doctor if**

- child experiences any of the following signs of stomach bleeding:
- feels faint
- vomits blood
- has bloody or black stools
- has stomach pain that does not get better
- pain gets worse or lasts more than 5 days
- any new symptoms appear
- redness or swelling is present in the painful area
- ringing in the ears or a loss of hearing occurs

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- **this product does not contain directions or complete warnings for adult use**
- administer only under adult supervision
- if possible, use weight to dose, otherwise use age
- repeat dose every 4 hours while symptoms last
- do not give more than 5 doses in 24 hours
- drink water with each dose

<b>Weight (lbs.)</b>	<b>Age (years)</b>	<b>Dose</b>
77 – 83	11 to under 12	4 – 6 tablets
66 – 76	9 to under 11	4 - 5 tablets
46 – 65	6 to under 9	4 tablets
36 – 45	4 to under 6	3 tablets
32 – 35	3 to under 4	2 tablets
under 32	under 3	ask a doctor

DRINK A FULL GLASS OF WATER WITH EACH DOSE

- **adults and children 12 years and older** : take 4 to 8 tablets every 4 hours while symptoms last, but not more than 48 tablets in 24 hours.
- **Children under 12 years** : ask a doctor

### Other Information

- store at 15-30 °C (59-86 °F)

### Inactive Ingredients

corn starch, FD&C Yellow #6 alum. lake, magnesium stearate, orange flavor, silicon dioxide, sugar

**Questions or Comments**

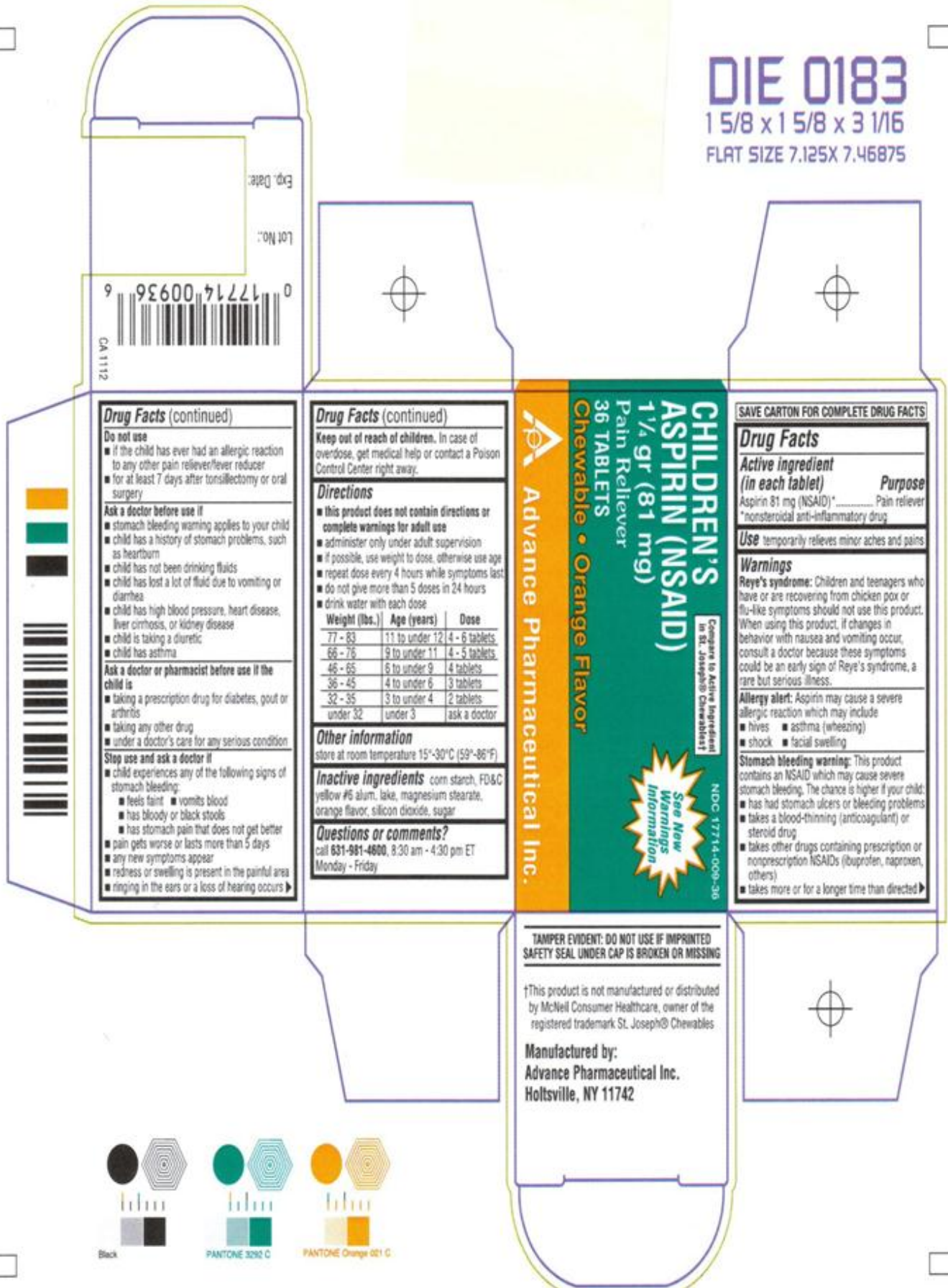
Call 631-981-4600, 8.30am – 4.30 pm ET Monday-Friday

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

**Manufactured by: Advance Pharmaceutical, Inc. Holtsville, NY 11742**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**DIE 0183**  
 1 5/8 x 1 5/8 x 3 1/8  
 FLAT SIZE 7.125X 7.46875



Exp. Date: \_\_\_\_\_  
 Lot No.: \_\_\_\_\_



CA 1112

**Drug Facts (continued)**

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- if the child has ever had an allergic reaction to any other pain reliever/fever reducer
- for at least 7 days after tonsillectomy or oral surgery

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**Drug Facts (continued)**

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store at room temperature 15°-30°C (59°-86°F)

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**Questions or comments?**

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 Monday - Friday

**CHILDREN'S ASPIRIN (NSAID)**  
 Pain Reliever  
 1 1/4 gr (81 mg)  
 36 TABLETS  
 Chewable • Orange Flavor  
 Advance Pharmaceutical Inc.  
 Compare to Active Ingredient in St. Joseph® Chewables  
 See New Warnings Information  
 NDC 17714-009-36

SAVE CARTON FOR COMPLETE DRUG FACTS

**Drug Facts**

**Active ingredient (in each tablet)** Aspirin 81 mg (NSAID)  
**Purpose** Pain reliever  
 \*nonsteroidal anti-inflammatory drug

**Use** temporarily relieves minor aches and pains

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include

- hives
- asthma (wheezing)
- shock
- facial swelling

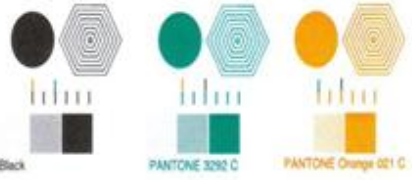
**Stomach bleeding warning:** This product contains an NSAID which may cause severe stomach bleeding. The chance is higher if your child:

- has had stomach ulcers or bleeding problems
- takes a blood-thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (ibuprofen, naproxen, others)
- takes more or for a longer time than directed

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark St. Joseph® Chewables

**Manufactured by:**  
 Advance Pharmaceutical Inc.  
 Holtsville, NY 11742



NDC 17714-009-36

# CHILDREN'S ASPIRIN (NSAID)

1 1/4 gr (81 mg)

Pain Reliever

36 TABLETS

Chewable

Orange Flavor



**SEE CARTON FOR COMPLETE DRUG FACTS**

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**Directions** ■ this product does not contain directions or complete warnings for adult use ■ administer only under adult supervision ■ if possible, use weight to dose, otherwise use age ■ repeat dose every 4 hours while symptoms last ■ do not give more than 5 doses in 24 hours ■ drink water with each dose

**77-83 lbs. (11-under 12 yrs):** 4-6 tablets, **66-76 lbs. (9-under 11 yrs):** 4-5 tablets, **46-65 lbs. (6-under 9 yrs):** 4 tablets, **36-45 lbs. (4-under 6 yrs):** 3 tablets, **32-35 lbs. (3-under 4 yrs):** 2 tablets, **under 32 lbs. (under 3 yrs):** ask a doctor

Store at room temperature 15°-30°C (59°-86°F)

☎ 631-981-4600

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



LA0710

Lot No.:  
Exp. Date:

NDC: 17714-009-36 – 36 COUNT

**ASPIRIN**

aspirin tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17714-009
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ORANGE (UNII: 5EVU04N5QU)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	score with uneven pieces
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	AP;009
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17714-009-36	36 in 1 BOTTLE	04/15/1988	
1		1 in 1 CARTON; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part343	04/15/1988	

**Labeler** - Advance Pharmaceutical Inc. (078301063)**Registrant** - Advance Pharmaceutical Inc. (078301063)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Advance Pharmaceutical Inc.		078301063	manufacture(17714-009)

